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09/623,038	11/27/2000	George M. Carlone	65446	5598

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c/o NEEDLE & ROSENBERG P.C.
999 PEACHTREE STREET
SUITE 1000
ATLANTA, GA 30309

EXAMINER	
DEVI, SARVAMANGALA J N	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 10/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/623,038	CARLONE ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,6,7,12-14,17 and 19-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2, 12, 20 and 23-26* is/are rejected.

7)☒ Claim(s) *6* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Applicants' Amendment

Applicants' Amendment

1) Acknowledgment is made of Applicants' amendment filed 07/21/05 in response to the non-final Office Action mailed 04/19/05. With this, Applicants have amended the specification and claims.

Status of Claims

2) Claims 15, 16 and 18 have been canceled via the amendment filed 07/21/05.

Claims 2, 6, 12, 20 and 23 have been amended via the amendment filed 07/21/05.

New claims 24-26 has been added via the amendment filed 07/21/05.

Claims 2, 6, 7, 12-14, 17 and 19-26 are pending.

Claims 2, 6, 12, 20 and 23-26 are under examination.

The Sampson Declaration

3) Acknowledgment is made of Applicants' submission of the Sampson declaration filed 07/21/05. The declaration states that the hybridoma 1B6E12H9 having the ATCC accession number PTA-6531 is the same hybridoma that is described in the specification and was in their possession at the time of filing of the priority application, 60/076,565. Attached to the declaration is a notice of deposit of the hybridoma from the ATCC.

Prior Citation of Title 35 Sections

4) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

5) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Rejection(s) Moot

6) The rejection of claim 15 made in paragraph 21 of the Office Action mailed 04/19/05 under 35 U.S.C. § 112, first paragraph, as containing inadequate written description, is moot in

light of Applicants' cancellation of the claim.

7) The rejection of claims 15, 16 and 18 made in paragraph 22 of the Office Action mailed 04/19/05 under 35 U.S.C § 112, first paragraph, as being non-enabled with regard to the scope, is moot in light of Applicants' cancellation of the claims.

8) The rejection of claims 16 and 18 made in paragraphs 23(c), 23(e) and 23(h) of the Office Action mailed 04/19/05 under 35 U.S.C § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claims.

9) The rejection of claims 15, 16 and 18 made in paragraph 24 of the Office Action mailed 04/19/05 under 35 U.S.C § 102(e) as being anticipated by Sampson *et al.* (US 6,217,884, already of record) ('884) as evidenced by Jarecki-Black (US 6,368,603), is moot in light of Applicants' cancellation of the claims.

Rejection(s) Withdrawn

10) The rejection of claim 2 made in paragraph 12 of the Office Action mailed 08/27/03 and maintained in paragraph 20 of the Office Action mailed 07/23/04 and paragraph 14 of the Office Action mailed 04/19/05 under 35 U.S.C. § 112, first paragraph, with regard to the deposit issue, is withdrawn in light of Applicants' amendments to the claim and the specification, and Applicants' compliance with the deposit rules.

11) The rejection of claim 6 made in paragraph 19 of the Office Action mailed 04/19/05 under 35 U.S.C. § 112, first paragraph, as containing new subject matter, is withdrawn in light of Applicants' amendment to the claim.

12) The rejection of claims 12 and 20 made in paragraph 20 of the Office Action mailed 04/19/05 under 35 U.S.C. § 112, first paragraph, as containing new subject matter, is withdrawn in light of Applicants' amendment to the claims.

13) The rejection of claims 12 and 20 made in paragraph 22 of the Office Action mailed 04/19/05 under 35 U.S.C § 112, first paragraph, as being non-enabled with regard to the scope, is withdrawn in light of Applicants' amendment to the claims.

14) The rejection of claim 2 made in paragraph 23(a) of the Office Action mailed 04/19/05 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants'

amendment to the claim.

15) The rejection of claim 6 made in paragraphs 23(b) and 23(d) of the Office Action mailed 04/19/05 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

16) The rejection of claims 12 and 20 made in paragraph 23(f) of the Office Action mailed 04/19/05 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims.

17) The rejection of claim 23 made in paragraph 23(g) of the Office Action mailed 04/19/05 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

18) The rejection of claim 6 made in paragraph 23(h) of the Office Action mailed 04/19/05 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the base claim.

19) The rejection of claim 6 made in paragraph 25 of the Office Action mailed 04/19/05 under 35 U.S.C § 102(b) as being anticipated by Nuijens *et al.* (WO 9117258, already of record) as evidenced by Srivastava *et al.* (*Hybridoma* 19: 23-31, 2000, already of record) and Harlow *et al.* (*In*: *Antibodies*: *A Laboratory Manual*. Cold Spring Harbor Laboratory, Chapter 5, p. 76, 1988, already of record), is withdrawn in light of Applicants' amendment to the claim.

20) The rejection of claims 6, 12 and 20 made in paragraph 24 of the Office Action mailed 04/19/05 under 35 U.S.C § 102(e) as being anticipated by Sampson *et al.* (US 6,217,884, already of record) ('884) as evidenced by Jarecki-Black (US 6,368,603), is withdrawn in light of Applicants' amendment to the claims.

21) The provisional rejection of claims 12 and 20 made in paragraph 18 of the Office Action mailed 04/19/05 under the judicially created doctrine of obviousness-type double patenting over claim 11 of the then pending application SN 09/613,092, is withdrawn since this application is now issued. A modified double patenting rejection is set forth below.

22) The rejection of claim 23 made in paragraph 24 of the Office Action mailed 04/19/05 under 35 U.S.C § 102(e) as being anticipated by Sampson *et al.* (US 6,217,884, already of record) ('884)

as evidenced by Jarecki-Black (US 6,368,603), is withdrawn.

Rejection(s) Maintained

23) The rejection of claim 2 made in paragraph 18 of the Office Action mailed 08/27/03 and maintained in paragraph 23 of the Office Action mailed 07/23/04 and paragraph 15 of the Office Action mailed 04/19/05 under 35 U.S.C § 102(e) as being anticipated by Sampson *et al.* (US 6,217,884, already of record), is maintained for reasons set forth therein and herebelow.

Applicants contend that: (a) Claim 2 is directed to a purified peptide that immunospecifically binds to the monoclonal antibody designated 1B6E12H9 and deposited with the ATCC; (b) Sampson *et al.* recite only the laboratory designation for a monoclonal antibody. Based on the proper analysis with regard to enablement of monoclonal antibodies articulated in the Office Actions, antibody 1B6E12H9 was not sufficiently disclosed to have been enabled in the 6,217,884 patent; (c) Sampson *et al.* shows that the full-length PsaA binds to the antibodies for which they provide laboratory designations, and does not show that any purified peptide binds to any antibody mentioned; (d) Because the antibody was not enabled in Sampson *et al.*, a peptide that immunospecifically binds the antibody, which is not otherwise enabled cannot be enabled in that reference. Since a reference must enable an invention to anticipate it, Sampson *et al.* does not anticipate claim 2.

Applicants' arguments have been carefully considered, but are not persuasive. First, the product claimed in the instant application is not the monoclonal antibody identified by the laboratory designation, 1B6E12H9. Instead, what is claimed is a peptide of unspecified length and unspecified structure. Claim 2 does not place a size or structure limit on the claimed peptide. The term 'peptide' is defined in the art as a compound having a peptide bond(s) and two or more amino acid residues. See page 1051 of *Illustrated Stedman's Medical Dictionary*, 1982. Therefore, Sampson's full-length polypeptide, the unique fragment of the polypeptide, or the peptide having the selective binding ability (see all of column 12; and lines 52-59 in column 11) meets the instantly claimed 'peptide'. Contrary to Applicants' assertion, Sampson *et al.* do not teach any peptide having no specific function(s). Instead, Sampson *et al.* expressly taught 37-kDa PsaA peptide necessarily having selective immunoreactivity with the antibodies described. For instance, Sampson *et al.* expressly taught that their 37-kDa PsaA peptide 'must' possess the property of

immunoreactivity (see first full sentence in column 12). Moreover, it should be noted that Sampson's purified 37 kDa full-length PsaA polypeptide itself is included in the scope of instant claim 2 given the art-recognized definition of 'peptide'. Consistent with Applicants' own acknowledgment, Sampson's purified PsaA polypeptide (which contains more than two amino acid residues) binds to the monoclonal antibodies, including the one having the laboratory designation, 1B6E12H9. Irrespective of whether the monoclonal antibody is referred to by its laboratory designation or by its ATCC deposit designation, the 1B6E12H9 monoclonal antibody is still the same monoclonal antibody that is recited in the instant claim 2, which antibody was already in possession of Sampson *et al.* before the instant invention. As stated in 35 U.S.C 282, a patent shall be presumed valid. In view of the statutory presumption of validity and the express disclosure of the 1B6E12H9 monoclonal antibody-reactive polypeptides, peptides or fragments thereof, the Sampson '884 patent is presumed valid and therefore is presumed to contain fully enabling disclosure. See *In re Lamberti*, 545 F.2d 747, 751 n.2, 192 USPQ 278, 281 n.2 (CCPA 1976); *In re Jacobs*, 318 F.2d 743, 137 USPQ 888 (CCPA 1963); and *In re Michalek*, 162 F.2d 229, 74 USPQ 107 (CCPA 1947). The rejection stands.

24) The rejection of claims 2 and 23 made in paragraph 25 of the Office Action mailed 04/19/05 under 35 U.S.C § 102(b) as being anticipated by Nuijens *et al.* (WO 9117258, already of record) as evidenced by Srivastava *et al.* (*Hybridoma* 19: 23-31, 2000, already of record) and Harlow *et al.* (*In*: *Antibodies*: *A Laboratory Manual*. Cold Spring Harbor Laboratory, Chapter 5, p. 76, 1988, already of record), is maintained for reasons set forth therein and herebelow.

Applicants present the following arguments. As stated in the Office Action, Nuijens *et al.* disclose a purified peptide that comprises SYQHDL, which is 'identical' to the SYQHDL sequence within SEQ ID NO: 6. Claims 2 and 23 are directed to peptides that immunospecifically bind monoclonal antibody 1B6E12H9, enabled by its deposit with the ATCC. There was no enabling disclosure of monoclonal antibody 1B6E12H9 in the art. There is only a 6 amino acid overlap between the 15 amino acid peptide of SEQ ID NO: 6 and the 12 amino acid peptide disclosed in Nuijens *et al*. The Patent Office has taken the position that neither a segment of SEQ ID NO: 6 (e.g., the 6-mer of Nuijens *et al.*) nor a peptide with 90% similarity to SEQ ID N0: 6 were enabled, *inter alia*, due to lack of predictability of function of segments or variants of SEQ ID N0: 6. Yet, the present

Office Action treats the disclosure in Nuijens *et al.* of an even more divergent 12-mer peptide having a fragmentary overlap with SEQ ID NO: 6 as anticipatory of immunospecific binding with an antibody that was not disclosed in the art. In order for a reference to anticipate an invention, the reference must enable the invention. There is no evidence in Nuijens *et al.* that enables immunospecific binding with the monoclonal antibody recited in claims 2 and 23. The fact that there is an area of exact overlap between the exemplified peptide and the prior art peptide, which are otherwise significantly different, does not support a conclusion that the prior art peptide possesses the binding characteristic that define claim 2. In fact the 6-amino acid overlap constitutes only about 40% similarity with SEQ ID NO: 6. By the Office's own reasoning, this is not sufficient to enable the recited immunospecifcally binding peptide. In contrast, by enabling the recited monoclonal antibody, Applicants enable the immunospecifically binding peptides. Since the art must enable the invention in order to anticipate it, this rejection of claims 2 and 23 should fail. The fact that Nuijens *et al.* is silent on the issue of binding is crucial, as the absence of such evidence means that the reference does not explicitly teach the invention. There is no evidence or even suggestion in Nuijens *et al.* that their peptide would immunospecifically bind monoclonal antibody 1B6E12H9. For a peptide that is only 40% related, by the Office's own reasoning there is no basis to assert that binding would be similar. Such an assertion is also inconsistent and nonsensical in view of the Office's application of the enablement standard. Thus, the burden shifting referred to on page 33 is not justified. If the Office is trying to make an inherency rejection, a key requirement of inherency is missing, i.e., that the claimed invention was necessarily practiced in the prior art. Such a rejection cannot be based on a reasonable or statistical likelihood that the claimed composition was present. There is no such certainty in the Nuijens *et al.* reference even when read in retrospect with the knowledge of the present invention. There is no credible scientific support for a conclusion that Nuijens *et al.* either teach the peptides of claims 2 and 23 or inherently anticipates them.

Applicants' arguments have been carefully considered, but are not persuasive. Applicants appear to be mixing up the standards set under two separate statutes, i.e., 35 U.S.C § 102 and 35 U.S.C § 112, first paragraph. Applicants are reminded that what is being claimed is not a monoclonal antibody produced by the hybridoma 1B6E12H9, but a peptide. Contrary to Applicants' assertion, the monoclonal antibody 1B6E12H9 was already disclosed in the art at the

time of the invention by Sampson *et al.* ('884). Contrary to Applicants' argument, the Office has not taken the position that Nuijens' specific 6-mer SYQHDL which shows 100% sequence identity to the SYQHDL 6-mer of Applicants' SEQ ID NO: 6 was non-enabled. Instead, the Office has consistently maintained the position that, as clearly evidenced by Srivastava *et al.*, the 6 amino acid-long peptide SYQHDL of the amino acid sequence of SEQ ID NO: 6 is not excluded from the scope of the claims. Instead, six amino acid-long peptides are expressly included within the scope of the invention. See first full paragraph on page 22 of the specification. The peptide claimed in claims 2 and 23 continues to lack structure or size limit. The specification in the first full paragraph on page 19 of the specification expressly states as follows:

> In addition, the invention encompasses immunogenic peptides which may be shorter than these sequences. Thus for example immunogenic fragments of SEQ ID NO: 5, immunogenic fragments of SEQ ID N0: 6, immunogenic fragments of SEQ ID N0: 7, and immunogenic fragments of SEQ ID NO:8 are also encompassed by the present invention.

Claims 2 and 23 do not require a fifteen amino acids overlap between the prior art peptide and the 15 amino acid peptide of SEQ ID NO: 6. The fact that there is an area of exact 100% sequence match between a peptide in Applicant's SEQ ID NO: 6 and the prior art peptide SYQHDL, supports the conclusion that the prior art peptide necessarily possesses the recited binding characteristic, particularly as evidenced by the disclosure of Srivastava *et al.* and Applicants' own description at first full paragraph on page 22 and page 19. Applicants' argument that the 6-amino acid overlap is not sufficient to enable the recited immunospecifcally binding peptide is contrary to Applicants' own express disclosure in the first paragraph of page 22 of the specification, wherein Applicants acknowledge that it is generally understood in the field of immunochemistry that peptides six residues in length are indeed antigenic. Thus, by Applicants' own admission, the hexapeptide SYQHDL portion of the prior art peptide which overlaps with the SYQHDL portion of Applicants' SEQ ID NO: 6, is fully enabled as being antigenic and therefore necessarily serves as an immunospecifically binding peptide as evidenced by Srivastava's express showing that SYQHDL is indeed an intrinsic part of the 1B6E12H9-binding site of Applicants' SEQ ID NO: 6. See last five lines in the right column of page 24; Table 1; and the top most rectangular box in Figure 1 of Srivastava *et al.* Clearly, Nuijens *et al.* teach the structural limitations of the claims. The 'immunospecific binding' as recited is a functional limitation inherent to and inseparable from the prior art peptide, SYQHDL. The rejection stands.

Extra references and extra evidence can be used to show that the primary reference contains an enabling disclosure and that a characteristic not disclosed in the reference is inherent. See MPEP 2131.01. 'To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.' *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991). Note that as long as there is evidence of record establishing inherency, failure of those skilled in the art to contemporaneously recognize an inherent property, function or ingredient of a prior art reference does not preclude a finding of anticipation. *Atlas Powder Co. v. IRECO Inc.*, 190 F.3d 1342, 1349, 51 USPQ2d 1943, 1948 (Fed. Cir. 1999). Also note that the critical date of extrinsic evidence showing a universal fact need not antedate the filing date. See MPEP 2124. In the instant application, Applicants have failed to advance any arguments with regard to the extra evidence provided via the teachings of Srivastava *et al.* It must be noted herein that the reference of Srivastava *et al.* is co-authored by five of the inventors of the instant application, GM Carlone, EW Aedes, JS Sampson, JL Zeiler and MAJ Westerink.

New Rejection(s) Based on Applicants' Amendments

The new rejections set forth below are necessitated by Applicants' amendments to the claim(s) and submission of new claims.

Double Patenting

25) Claims 12 and 20 are rejected under the judicially created doctrine of obviousness type double patenting over claim 1 of the US patent 6,903,184. Although the conflicting claims are not identical, they are not patentably distinct from each other because of their overlapping scope with regard to the peptide of SEQ ID NO: 6. The structure of the peptide of SEQ ID NO: 6 disclosed and/or claimed in the two applications is identical. Although claim 1 of the patent '184 does not teach a composition comprising the peptide of SEQ ID NO: 6 and an adjuvant or immunostimulatory carrier as recited in the instant claims, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to add an art-known immunostimulatory carrier or an adjuvant to the peptide claimed in the '184 patent to produce the therapeutic composition of the

instant invention, with a reasonable expectation of success. One of skill in the art would have been motivated to produce the instant invention for the expected benefit of providing the peptide of SEQ ID NO: 6 of the '184 patent beneficially as a composition with adjuvant or immune-enhancing properties since such a composition is ideally desired in the art.

Rejection(s) under 35 U.S.C § 101

26) Claims 12 and 20 are rejected under 35 U.S.C § 101 as being directed to a non-statutory subject matter.

Claims 12 and 20 do not sufficiently distinguish over a naturally occurring peptide composition comprising the amino acid sequence of SEQ ID NO: 6 and an immunostimulatory carrier or adjuvant as it exists naturally, for example, on the surface of *S. pneumoniae*, because the claims do not particularly point out any non-naturally occurring differences between the claimed product and the naturally occurring products, such as whole cell compositions comprising SEQ ID NO: 6 and an intrinsic cell wall peptidoglycan immunostimulatory carrier or adjuvant. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty, 447 U.S. 303, 206 USPQ 193 (1980)*. The base claim(s) should be amended to indicate the hand of the inventor, e.g., by insertion of --a purified peptide--, as claimed for example in claim 2. See MPEP 2105.

Rejection(s) under 35 U.S.C § 112, First Paragraph (New Matter)

27) Claims 24-26 are rejected under 35 U.S.C § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

New claims 24-26 include the limitation: 'in claim 2, wherein the peptide is 10-25 residues in length'; 'in claim 2, wherein the peptide is 12-22 residues in length'; and 'in claim 2, wherein the peptide is 15 residues in length'. Applicants state that claims 3-5 as filed provide descriptive support for the new claims. However, the original claims 3-5 had nothing to do with SEQ ID NO: 6 or a peptide thereof that is 10-25, 12-22, or 15 residues in length. The original claims 24-26 were not associated with any specific SEQ ID number. The description provided at lines 26-28 on page 22 of the specification is limited to fragments of 'SEQ ID NO: 2' whose length is 10-25

residues, 12-22 residues, or about 15 residues. Therefore, the above-identified limitations in the new claims are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to point to the descriptive support in the specification as filed, for the limitations in the new claims, or remove the new matter from the claim(s).

Rejection(s) under 35 U.S.C § 112, Second Paragraph

28) Claims 24-26 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claims 24-26 are vague and indefinite in the limitation: 'peptide described in claim 2'. For the purpose of distinctly claiming the subject matter, it is suggested that Applicants replace the limitation with --peptide claimed in claim 2--.

(b) Claims 24 and 25 are indefinite, confusing, nonsensical and/or incorrect in the limitation: '10-... residues in length' and '12-... residues in length', because a peptide 10, 11, 12, 13 or 14 amino acid residues in length cannot comprise the much longer amino acid sequence of SEQ ID NO: 6, which is fifteen amino acids in length.

Rejection(s) under 35 U.S.C § 102

29) Claims 12 and 20 are rejected under 35 U.S.C § 102(b) as being anticipated by Tharpe *et al.* (*Clin. Diagnost. Lab. Immunol.* 3: 227-229, 1996, already of record) as evidenced by *Illustrated Stedman's Medical Dictionary* (24th Edition, Williams & Wilkins, Baltimore/London, page 1051, 1982) and Norcross *et al.* (US 4,425,330).

It is noted that the peptide recited in claims 12 and 20 is not required to be isolated and purified. It is further noted that the transitional recitation in the claims 'comprising' is open-ended claim language and therefore does not exclude additional, unrecited elements. See MPEP 2111.03 [R-1].

It is noted that the term 'peptide' is defined in the art as a compound that contains a peptide bond and two or more amino acids. See page 1051 of *Illustrated Stedman's Medical Dictionary*,

1982. Therefore, a compound having peptide bonds and more than two amino acids qualifies as a 'peptide'.

Tharpe *et al.* taught a composition comprising PBS and a whole-cell suspension of *Streptococcus pneumoniae* type 22F comprising a 37 kDa protein of *S. pneumoniae* (see page 227, particularly paragraph bridging the two columns). The prior art composition is expected to inherently comprise a peptide comprising the instantly recited amino acid sequence of SEQ ID NO: 6. Although Tharpe *et al.* are silent about the SEQ ID number as recited in the instant claims, since the prior art *S. pneumoniae* type 22F strain used for the whole cell composition is the same type 22F *S. pneumoniae* strain used by Applicants to produce the recited monoclonal antibody (see lines 5 and 6 on page 27 of the instant specification), the prior art composition is viewed as necessarily comprising the peptide of SEQ ID NO: 6, and therefore is expected to have the same structure of SEQ ID NO: 6, absent evidence to the contrary. Furthermore, that the prior art *S. pneumoniae* type 22F whole cell composition intrinsically comprised a natural adjuvant or immunostimulatory carrier is also inherent from the teachings of Tharpe *et al.* in light of what was known in the art. For instance, it was known in the art at the time of the invention that Gram positive bacterial cell walls, including those from *Streptococcus* species, comprise intrinsic immunopotentiators, such as peptidoglycan. See the full paragraph below 'Introduction' in column 26 of Norcross *et al.*

Claims 12 and 20 are anticipated by Tharpe *et al.* The reference of Norcross *et al.* or the *Illustrated Stedman's Medical Dictionary* is **not** used as a secondary reference in combination with Tharpe *et al.*, but rather is used to show that every element of the claimed subject matter is disclosed by Tharpe *et al.* See *In re Samour* 197 USPQ 1 (CCPA 1978).

Remarks

30) Claims 2, 12, 20 and 23-26 stand rejected. Claim 6 is objected for being dependent from a rejected claim.

31) Applicants' amendments necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 C.F.R 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the

mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

32) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Fax number for submission of amendments, responses or papers is (571) 273-8300.

33) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

34) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

S. DEVI, PH.D.
PRIMARY EXAMINER

September, 2005